



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

To: Julie Breeden-Alemi, DVM

From: Virna Stillwaugh, Ph.D., Entomologist

Secondary Review: Pesticide Efficacy Review Committee (PERC)

Date: November 29, 2018

Subject: REBUTTAL TO DP 448822 October 23, 2018

THIS DER DOES NOT CONTAIN CONFIDENTIAL BUSINESS INFORMATION

Note: MRIDs found to be **unacceptable** to support label claims should be removed from the data matrix.

DP barcode: 449838

Decision no.: 542157

Submission no: 1027444

Action code: R340

Product Name: FRONTLINE ACTIVE FOR DOGS

EPA Reg. No or File Symbol: 65331-9

Formulation Type: topical spot-on solution

Ingredients statement from the label with PC codes included:

Fipronil 6.01%, PC Code - 129121

Permethrin 44.88%, PC Code - 109701

Pyriproxyfen 1.8%, PC Code - 129032

Application rate(s) of product and each active ingredient (lbs. or gallons/1000 square feet or per acre as appropriate; and g/m² or mg/cm² or mg/kg body weight as appropriate): Ready to use topical spot on solution capsules containing 6.01% Fipronil, 44.88% Permethrin, and 1.8% Pyriproxyfen. Label includes text for two different applicator sizes:

- 4.0 mL applicator for dogs weighing 41-80 lbs
- 6.0 mL applicator for dogs weighing 81-120 lbs

Most conservative dose: 0.1 mL/kg

Body Weight Class	Amount of product to apply	Active Ingredient Doses (mg/kg)*
41-80 lbs (18.6 – 36.3 kg)	4 mL (4.48 g)	Fipronil 7.4 mg/kg to 14.47 mg/kg Permethrin 55.4 mg/kg to 108.1 mg/kg
81-120 lbs (36.7- 54.4 kg)	6 mL (6.72 g)	Fipronil 7.4 mg/kg to 11 mg/kg

		Permethrin 55.4 mg/kg to 82.2 mg/kg
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*Based on product density of 1.122 g/mL @ 20 °C

Use Patterns: Spot-on solution for external use on dogs to control ticks, fleas and mosquitoes. Not for use on dogs weighing less than 41 lbs.

I. Action Requested: The registrant submitted a rebuttal to an efficacy review dated October 23, 2018 (DP 448822). Merial submitted alternate proposed speed of kill claims in an email (dated 10/29/18) and a subsequent cover letter (dated 11/13/18).

II. Background: Originally, the registrant submitted an action to add speed of kill claims for fleas and ticks to the label for EPA Reg. No. 65331-9 (see MRID 50617601). A 10-day letter was sent to the registrant regarding a data deficiency for ticks. In their 10-day letter response, the registrant stated that they are now submitting data (MRID 50617602) to support the addition of speed of kill claims for fleas only. Data supported the following efficacy claim, “kills fleas within 6 hours, beginning 2 days after product application”.

III. Rebuttal Summary:

Merial rebuttal points 1 and 2: “Starts working against fleas in 5 minutes beginning 2 days after treatment”; “Starts working quickly against fleas, [beginning] 2 days after treatment”

Agency Response: As stated previously in the efficacy review dated October 23, 2018 (RDEFFICACY 65331-9 (448822) 20181023), data did not support quick kill (“starts killing”) claims for fleas for 1 or 5 min because moribund and dead insects were combined in the “dead” category and moribund insects were not held for 48 hrs to confirm mortality. Although the registrant included moribund in their mortality counts, mortality of moribund insects was not confirmed. The claim “starts working” was discussed with the PERC committee and it was decided that “starts working” would require that any moribund fleas counted would still need to be confirmed to later die, just as the “starts killing” claim would.

Merial rebuttal point 3: “Starts repelling fleas in 5 minutes[beginning], 2 days after treatment”

Agency Response: No data for repellency were submitted; therefore, this claim is not supported.

IV. EXECUTIVE DATA SUMMARY: Refer to the efficacy review dated October 23, 2018 (DP 448822); RDEFFICACY 65331-9 (448822) 20181023).

No new claims are supported with this rebuttal.

[Note: MRID 50617602 is incorrectly labeled as 50617601 in the EXECUTIVE SUMMARY section (page 4) of the review dated October 23, 2018]

Draft Master Label

[Optional text appears in brackets. The final label may include some or all of the optional text on the front, back, side panels, of carton, insert, or compliance card]

Front Panel {3, and 6 Applicator Carton}{Single Applicator Package Insert}

{Note to reviewer: The package insert for the single applicator presentation is a bi-fold insert with the front panel and part of the back panel visible through the packaging. The Master label includes label text for two different applicator sizes corresponding to two dog weight ranges, including a single for the 4.0 mL applicator, and a [3][6] applicator presentation for the 6.0 mL applicator. Due to space limitations the layout of the single applicator label differs from the [3][6] applicator labels since the single applicator label does not include a carton or compliance card. A large, clear picture of a dog in the appropriate weight range for the product as packaged will be placed on the front panel. For alternate marketing text, see pages 19-25}

FRONTLINE® SHIELD for Dogs
[ABN] FRONTLINE® ACTIVE for Dogs
[ABN] FRONTLINE® ULTRA for Dogs
[ABN] FRONTLINE® REPEL for Dogs
[ABN] FRONTLINE® EXTRA for dogs
[From the maker of FRONTLINE]

[1][3][6]
monthly
dose(s)

[Note to the Reviewer: The "Dog" text size will be 75% of the height of the largest letter in the primary brand name.]

Picture of
representative
size dog

[PICTOGRAMS: icon with slash through]

[Adult Flea]

[Flea eggs]

[Flea larvae]

[Flea pupae]

[Adult Tick]

[Chewing Lice]

[Mosquitoes]

[Stable Flies]

[Sand Flies]

[Sarcoptes mange mites]

TICKS

[Repels and Kills Ticks]

FLEAS

[Starts killing fleas [in][in as][quickly][as] 5 minutes]

[Repels and [Quickly] Kills Fleas]

[Starts working against fleas [in][in as][quickly][as] 5 minutes, [beginning] 2 days after treatment]

[Starts working quickly against fleas [[beginning] 2 days after treatment]]

[Kills all life stages of fleas]

[Plus]

MOSQUITOS

Comment [S01]: Added based on proposal in a comment on page 9 of the master label within the DER.

Reason to Issue: Label Amendment

Date: 09/11/18/2018
Supersedes: 07/31/2017

[Repels flying insects]
[Repels and Kills Mosquitos]
[Kills and Repels fleas and ticks]

[LONG-LASTING CONTROL for [up to] [one month] [30-days][4 weeks] OF FLEAS, TICKS MOSQUITOS, SAND FLIES, STABLE FLIES AND LICE]

[Repels ~~Fleas~~, Ticks, Mosquitoes, Sand Flies and Stable Flies]

[Kills Fleas, Flea eggs, and Flea larvae, Ticks, Stable Flies, Sand flies and Lice and aids in the control of sarcoptes mites]

[Kills fleas in 6 hours, beginning 2 days after application]

[Prevents [all flea stages] [(eggs ~~and~~ larvae ~~and pupae~~)] from developing]

For use on Dogs & Puppies ONLY 9 weeks or older and weighing [41-80] [81-120] lbs.

{Note to reviewer: Abbreviated text to be used for the large and extra-large dog weight bands. Smaller weight bands representative of puppy weight ranges will include Puppies and 9 weeks of age or older statement.}

KEEP OUT OF REACH OF CHILDREN WARNING

Front Panel {3 and 6 Applicator Carton}-For First Aid and additional Precautionary Statements, refer to carton back panel. For additional Directions for Use, refer to package insert.

Front Panel {Single Applicator Insert}- For First Aid, Precautionary Statements, and additional Directions for Use, refer to inner panels of package insert.

READ THE ENTIRE LABEL BEFORE EACH USE.

ACTIVE INGREDIENTS

Fipronil.....6.01%
Permethrin*.....44.88%
Pyriproxyfen1.8%

OTHER INGREDIENTS.....47.31%

TOTAL.....100.0%

* cis-trans ratio: max. 55% (+/-) cis and min. 45% (+/-) trans

1-[Net Contents :] [0.135] fl. oz. ([4.0] ml)

3-[Net Contents :] [0.609] fl. oz. ([18.0] ml)

6-[Net Contents :] [1.218] fl. oz. ([36.0] ml)



[1.5 x 1.5 cm]

{Note to the Reviewer: This 1.5cm x 1.5cm cat prohibition icon in yellow with black images will be located inside a box at the lower right hand corner of the front panel of the carton for the 3x, and 6x, presentations, and on the lower right hand corner of the front panel for the 1x package insert.}]

Front Panel - Reverse Side { 3 and 6 Applicator Carton }

{ Note to the Reviewer: The front panel of the carton is printed on both sides and perforated on the right edge of the carton. To open the carton and view the carton inside front panel, pull up on the right side of the front panel breaking the perforations to open, and by using a right-to-left motion, invert the front panel to view the carton inside front panel. }

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. **FOR EXTERNAL USE ON DOGS AND PUPPIES ONLY.** TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY.

RESTRICTIONS

Do not use on dogs or puppies under 9 weeks of age or weighing less than [41][81] lbs. DO NOT ALLOW CHILDREN TO APPLY PRODUCT. DO NOT TOUCH TREATED AREA UNTIL DRY. DO NOT ALLOW ADULTS, CHILDREN OR OTHER PETS TO TOUCH TREATED AREA UNTIL DRY. DO NOT USE ON CATS OR RABBITS. DO NOT USE ON ANIMALS OTHER THAN DOGS. Do not apply more than [once a month][every 30 days][every 4 weeks].

Do not allow your dog to ingest this product. Do not split applicators between dogs. Do not use multiple applicators on one dog. Do not apply more than once a month. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Do not apply more than one applicator per treatment for one dog regardless of the dog's weight. Overdosing your dog can result in serious illness. Do not bathe your dog within the first 24 hours after the product has been applied. Remember, your dog needs to be dry at the time **FRONTLINE® Shield for Dogs** is applied and remain dry 24 hours after application.

If your dog is exhibiting signs of and/or is being treated for skin problems, talk to your veterinarian before applying any topical flea and tick control product. Do not apply more often than [once a month][every 30 days][every 4 weeks].

For use on DOGS and PUPPIES ONLY 9 weeks or older and weighing at least [41][81] lbs to kill fleas and ticks and prevent fleas from developing; to repel and prevent blood-feeding by ticks, mosquitoes, sand flies and stable flies; to kill chewing lice and to aid in control of sarcoptes mange mites.

Front Panel - Reverse Side {3 and 6 Applicator Carton}

~~{Note to the Reviewer: Replace Step 4 of the instructions below with the appropriate size dog.}~~

FIRST AID	
IF SWALLOWED:	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have a person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
IF IN EYES:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
Have product container or label with you when calling a poison control center or doctor, or going for treatment, or call 1-800-660-1842 for 24-hour assistance.	

Comment [S02]: Moved to the Inside Front Panel Flaps with the How to Apply Directions that the note is referring to.

Comment [S03]: The first aid box is highlighted to indicate the placement has changed to be on the reverse of the front panel. The language in the First Aid box has not changed.

Back Panel {[3][6] Applicator Carton}

FRONTLINE® SHIELD for Dogs**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS and DOMESTIC ANIMALS****HAZARDS TO HUMANS**

WARNING. May cause substantial but temporary eye injury. Do not get in eyes or on clothing. Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash clothing that may have come in contact with the product before reuse.

HAZARDS TO DOMESTIC ANIMALS

For external use on dogs ONLY. Do not use on animals other than dogs. Do not use on dogs ~~or~~ puppies under 9 weeks of age or weighing less than [41][81] lbs. Individual sensitivities may occur after using ANY pesticide product. Dogs may experience some temporary irritation at the site of product application. If signs of sensitivity occur, bathe your dog with mild soap or shampoo and rinse with large amounts of water. If signs of sensitivity occur and persist, contact a veterinarian immediately. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs, or dogs known to be sensitive to pesticide products. This product is not a substitute for a prescribed heartworm preventative. Call 1-800-660-1842 Mon-Fri 8AM-8PM for assistance.

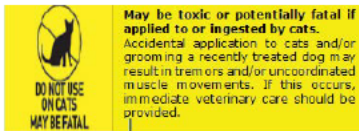
PHYSICAL OR CHEMICAL HAZARDS

Do not allow this product to come in contact with an oxidizing agent, a hazardous chemical reaction may occur.

Comment [S04]: "PHYSICAL OR CHEMICAL HAZARDS" Section is highlighted to indicate a change in placement. This section was moved above the side effects box to illustrate the actual placement on the carton label.

{Note to the Reviewer: A box labeled "Side Effects" will be placed immediately above the cat warning box on the back panel.}

Side Effects: Monitor your dog after application. Side effects, although very rare, may include signs of skin irritation such as redness, scratching, or other signs of discomfort. If these or other side effects occur, consult your veterinarian or call 1-800-660-1842.



[Note to the Reviewer: A 1.5cm x 1.5cm cat prohibition icon and warning text in a box will be located in the lower right hand corner of the back panel in yellow with black images]

Back Panel {[3][6] Applicator Carton}

Satisfaction
Guarantee
Icon

Please call our experts at 1-800-660-1842 if you have any questions or comments about flea, tick, mosquito, stable fly and lice control or **Frontline® Shield for Dogs**. If you have purchased this product from a veterinary clinic and are not satisfied with its performance as per the label, Merial may provide replacement product or refund of the purchase price. Please call Merial for details.

[PICTOGRAMS: icon with slash through]

[Adult Flea]

[Flea eggs]

[Flea larvae]

[Flea pupae]

[Adult Tick]

[Chewing Lice]

[Mosquitoes]

[Stable Flies]

[Sand Flies]

[Sarcoptes mange mites]

Merial Inc.
3239 Satellite Blvd.
Duluth, GA 30096-4640, USA
MADE IN FRANCE




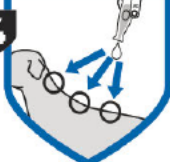
EPA Reg. No. 65331-9
EPA Est. No.

Inside Front Panel Flaps {[3][6] Applicator Carton}

{Note to Reviewer: To view the inside carton flaps, see the previous note on how to open the carton front panel. Once the carton front panel is opened, the two carton inside flaps will be visible as they are folded under the carton front panel. Replace Step 4 of the instructions below with the appropriate size dog. Step 4 will display the number of application sites relevant to the directions for the weight band of the product.}

Apply [monthly][every 30 days][every 4 weeks] according to the following directions:

How to Apply FRONTLINE® Shield for Dogs:

<p>1</p>  <p>TO REMOVE Applicator: Prior to opening separate one blister by tearing along perforation.</p>	<p>3</p>  <p>HOLD Applicator Upright away from you and your dog's face, cut applicator tip with scissors to open. Do not get product in your dog's eyes or mouth.</p>
<p>2</p>  <p>TO OPEN, use scissors to cut along dotted line of single blister; then pull apart foil and remove the applicator. OR fold on line at corner, tear and open at slit and remove the applicator.</p>	<p>4</p>  <p>APPLY FRONTLINE® SHIELD Part dog's hair until skin is visible. Place applicator tip directly against exposed skin. Apply the product evenly to three spots on the dog's back, starting between the shoulder blades and continuing on to the second and third spots, squeezing the applicator until empty. Ensure that FRONTLINE® Shield for Dogs is not applied superficially on dog's hair.</p>

Comment [S05]: The How to Apply Section placement was moved to the inside front panel flaps. The color scheme of the pictograms in this section has also changed. The only content changes within this section are the update of the alternate brand name to FRONTLINE SHIELD.

FRONTLINE® Shield for Dogs

Kills and repels fleas and ticks; prevents fleas, flea eggs and flea pupae from developing; repels mosquitoes and kills and repels sand flies and stable flies; and kills chewing lice for [one month][30 days][4 weeks].
Fleas do not have to bite to die.

Comment [S06]: These statements are included in the front panel and in the marketing claims section written in several different ways. These statements will not be on the inside flaps of the cartons.

FRONTLINE® Shield for Dogs

FRONTLINE® Shield for Dogs kills and repels fleas and ticks. The active ingredients in **FRONTLINE® Shield** provide for [long lasting][control][up to one month][30 days][4 weeks][one month][one month of long lasting][up to one month of long lasting][control] of fleas, ticks, mosquitoes, stable flies, and chewing lice on dogs.

[PICTOGRAMS: icon with slash through]

[Adult Flea]

[Flea eggs]

[Flea larvae]

[Flea pupae]

[Adult Tick]

[Chewing Lice]

[Mosquitoes]

[Stable Flies]

[Sand Flies]

[Sarcoptic mange mites]

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Insert - Front Panel {3 and 6 Applicators}

{Note to the Reviewer: The package insert for the [3x][6x] presentation is a single page printed on both sides and placed inside the carton.}

FRONTLINE® Shield for Dogs

For use on dogs ~~and puppies~~ ONLY ~~9 weeks or older and~~ weighing at least [41][81] lbs.

Convenient, [long-lasting] [for up to one month][30 days][4 weeks][one month] **topical** treatment **to kill** fleas, ticks, and chewing lice, and repellency of mosquitoes, sand flies and stable flies.

ACTIVE INGREDIENTS

Fipronil.....	6.01%
Permethrin*.....	44.88%
Pyriproxyfen	1.8%
OTHER INGREDIENTS.....	47.31%
TOTAL.....	100.0%

*cis-trans ratio: max. 55% (+/-) cis and min. 45% (+/-) trans

KEEP OUT OF REACH OF CHILDREN
WARNING

For First Aid and additional Precautionary Statements, refer to carton back panel. For additional Directions for Use, refer to package insert.

FRONTLINE® Shield for Dogs

Kills ~~fleas, kills and repels fleas and~~ ticks; prevents fleas from developing; repels mosquitoes, sand flies and stable flies; and kills chewing lice

- Prevents development of flea eggs and flea larvae, effectively breaking the flea life-cycle
- Repels and prevents blood feeding by stable flies and mosquitoes for [a month] [up to a month] [30 days] [4 weeks]
- Repels and prevents blood feeding by sand flies for three weeks
- Effectively stops existing infestations and prevents re-infestations of fleas, ticks and chewing lice
- Kills ticks which may transmit Lyme disease, Rocky Mountain spotted fever, Anaplasmosis, Babesiosis, canine Ehrlichiosis or cause tick paralysis
- Kills fleas and ticks for an entire month, including **Deer ticks, Brown Dog ticks, American Dog ticks, and Lone Star ticks**
- Kills fleas which may cause flea allergy dermatitis
- Kills fleas that may transmit bartonellosis, ~~tularemia~~ and tapeworm
- Repels mosquitoes which may be a vector of heartworm (*Dirofilaria immitis*)
- **Repels mosquitoes that may carry [heartworm disease][and][West Nile][vector borne] disease[s]**
- Aids in control of sarcoptes ~~mange~~ mite infestations ~~which can cause sarcoptic mange~~.
- Can be used on dogs ~~and puppies~~ ONLY ~~9 weeks or older and~~ weighing at least [41] [81] lbs.

[1.5 x 1.5 cm]



Comment [S07]: Propose including the specific vector borne diseases in response to EPA comment.

Insert - Front Panel {3 and 6 Applicators}**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. **FOR EXTERNAL USE ON DOGS AND PUPPIES ONLY.** TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY.

RESTRICTIONS

Do not use on dogs ~~or puppies under 9 weeks of age or~~ weighing less than [41] [81] lbs. DO NOT ALLOW CHILDREN TO APPLY PRODUCT. DO NOT TOUCH TREATED AREA UNTIL DRY. DO NOT ALLOW ADULTS, CHILDREN OR OTHER PETS TO TOUCH TREATED AREA UNTIL DRY. DO NOT USE ON CATS OR RABBITS. DO NOT USE ON ANIMALS OTHER THAN DOGS. Do not apply more than [once a month][every 30 days][every 4 weeks].

Do not allow your dog to ingest this product. Do not split applicators between dogs. Do not use multiple applicators on one dog. Do not apply more than once a month. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Do not apply more than one applicator per treatment for one dog regardless of the dog's weight. Overdosing your dog can result in serious illness. Do not bathe your dog within the first 24 hours after the product has been applied. Remember, your dog needs to be dry at the time **FRONTLINE® Shield for Dogs** is applied and remain dry 24 hours after application.

If your dog is exhibiting signs of and/or is being treated for skin problems, talk to your veterinarian before applying any topical flea and tick control product. Do not apply more often than [once a month][every 30 days][every 4 weeks].

For use on DOGS ~~and PUPPIES ONLY 9 weeks or older and~~ weighing at least [41][81] lbs. To kill fleas and ticks and prevent fleas from developing; to repel and prevent blood-feeding by ticks, mosquitoes, sand flies and stable flies; to kill chewing lice and to aid in control of sarcoptes ~~mites~~ ~~mange~~ mites.

FREQUENCY OF APPLICATION

[Fleas, flea eggs, ~~and flea pupae~~, flea larvae][~~All life stages of fleas~~], ticks, and chewing lice infestations can be controlled with monthly applications of **FRONTLINE® Shield for Dogs**. Stable flies and mosquitoes are repelled by **FRONTLINE® Shield for Dogs** for [one month][30 days][4 weeks]. Sand flies are [killed][repelled] for 3 weeks by **FRONTLINE® Shield for Dogs**. **Fleas:** **FRONTLINE® Shield for Dogs** kills adult fleas for [one month][30 days][4 weeks]. Apply [monthly][every 30 days][every 4 weeks] if your dog has fleas that may cause flea allergy dermatitis (FAD), or if re-infestation is likely. **Ticks:** **FRONTLINE® Shield for Dogs** can kill ticks for [one month][30 days][4 weeks]. Apply [monthly][every 30 days][every 4 weeks] where tick control is consistently needed. **Lice:** **FRONTLINE® Shield for Dogs** can kill chewing lice for [one month][30 days][4 weeks]. Apply [monthly][every 30 days][every 4 weeks] where lice control is consistently needed. **Mites:** **FRONTLINE® Shield for Dogs** aids in the control of sarcoptes ~~mites~~ ~~mange~~ mites. **Stable flies and Mosquitoes:** When applied [monthly][every 30 days][every 4 weeks], **FRONTLINE® Shield for Dogs** repels and prevents blood feeding by stable flies and mosquitoes.

[**Stable flies:** **FRONTLINE® Shield for Dogs** kills stable flies for [one month][30 days][4 weeks].]

FRONTLINE® Shield for Dogs ~~completely~~ breaks the flea life cycle when used [on a monthly basis][every 30 days][every 4 weeks].

Comment [S08]: Since stable flies and mosquitos are addressed together two lines before this, will make this line optional.

Insert - Back Panel {[3][6] Applicators}

Wait [at least 30 days][one month][4 weeks] before re-application of **FRONTLINE® Shield for Dogs**. Avoid contact with treated area until dry. **FRONTLINE® Shield for Dogs** remains effective even after bathing, water immersion, or exposure to sunlight 24 hours after application. A [monthly][20 day][4 week] application of **FRONTLINE® Shield for Dogs** kills existing fleas and prevents new fleas from developing; kills all stages of ticks, chewing lice, and repels mosquitoes and stable flies.

Research demonstrates that **FRONTLINE® Shield for Dogs** remains effective even after bathing, water immersion, or exposure to sunlight 24 hours after application.

PESTICIDE STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

STORAGE: Store unused product in original container only in a cool dry place, out of reach of children and animals.

PESTICIDE DISPOSAL and CONTAINER HANDLING: Non-refillable container. Do not reuse or refill this container. **If empty:** Place in trash or offer for recycling, if available.

If partly filled: Call your local solid waste agency or 1-800-422-9874 for disposal instructions. Never place unused product down any indoor or outdoor drain.

How Supplied

For easy and convenient application, **FRONTLINE® Shield for Dogs** is available in sizes for large dogs ~~& puppies ONLY 9 weeks or older and~~ 41-80 lbs., and extra-large dogs ONLY ~~9 weeks or older and~~ 81-120 lbs.

WARRANTY

Seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. To the extent consistent with applicable law, buyer assumes all risk of use and handling of this material when such use and handling are contrary to the label instructions.

Questions or Comments?
Call: 1-800-660-1842,
Monday-Friday, 8am-8pm EST

EPA Reg. No. 65331-9

Merial, Inc.
3239 Satellite Blvd.
Duluth, GA 30096-4640, USA

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Single Applicator Insert { Left Inner Panel }

FRONTLINE® Shield for Dogs

For use ONLY on dogs ~~8 puppies 9 weeks or older and~~ weighing at least [41][81] lbs.

Convenient, [long-lasting][for up to 30 days][monthly][for up to one month] ~~spot-on topical~~ for treatment of fleas, ticks, and chewing lice, and repellency of mosquitoes and stable flies.

FRONTLINE® Shield for Dogs

Kills fleas and ticks; prevents fleas from developing; repels mosquitoes, sand flies and stable flies; and kills chewing lice

- Prevents development of flea eggs, ~~and~~ flea larvae, ~~and flea pupae~~, breaking the flea life cycle
- Repels and prevents blood feeding by stable flies and mosquitoes for [up to a month][30 days][4 weeks]
- Stops existing infestations and prevents re-infestations of fleas, ticks and chewing lice
- Kills ticks which may transmit Lyme disease, Rocky Mountain spotted fever, Anaplasmosis, Babesiosis, canine Ehrlichiosis or cause tick paralysis
- Kills fleas and ticks for an entire month, including **Deer ticks, Brown Dog ticks, American Dog ticks, and Lone Star ticks**
- Kills fleas which may cause flea allergy dermatitis
- Kills fleas that may transmit bartonellosis, ~~tur~~ ~~rel~~ ~~are~~ ~~m~~ ~~i~~ ~~a~~ ~~n~~ ~~e~~ ~~m~~ ~~i~~ ~~a~~ and tapeworm
- Repels mosquitoes which may be a vector of heartworm (*Dirofilaria immitis*)
- Aids in control of sarcoptic mange infestations
- Can be used on dogs ~~and puppies~~ ONLY ~~9 weeks or older and~~ weighing at least [41][81] lbs.

DO NOT USE ON CATS – MAY BE FATAL

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS and DOMESTIC ANIMALS

HAZARDS TO HUMANS

WARNING: May cause substantial but temporary eye injury. Do not get in eyes or on clothing. Harmful if swallowed or absorbed through the skin. Avoid contact with skin. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash clothing that may have come in contact with the product before reuse.

HAZARDS TO DOMESTIC ANIMALS

For external use on dogs ONLY. Do not use on animals other than dogs.

Do not use on dogs ~~or puppies under 9 weeks of age or~~ weighing less than [41][81] lbs.

Individual sensitivities may occur after using ANY pesticide product. Dogs may experience some temporary irritation at the site of product application. If signs of sensitivity occur, bathe your dog with mild soap or shampoo and rinse with large amounts of water. If signs of sensitivity occur and persist, contact a veterinarian immediately. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs, or dogs known to be sensitive to pesticide products. This product is not a substitute for a prescribed heartworm preventative. Call 1-800-660-1842 **Mon-Fri from 8AM-8PM** for assistance.

Single Applicator Insert {Left Inner Panel}**PHYSICAL OR CHEMICAL HAZARDS**

Do not allow this product to come in contact with an oxidizing agent, a hazardous chemical reaction may occur.

FIRST AID	
IF IN EYES:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
IF SWALLOWED:	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have a person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
Have product container or label with you when calling a poison control center or doctor, or going for treatment, or call 1-800-660-1842 Mon – Fri from 8AM-8PM for assistance.	

Single Applicator Insert {Right Inner Panel}**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. **FOR EXTERNAL USE ON DOGS AND PUPPIES ONLY.** TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY.

RESTRICTIONS

Do not use on dogs ~~or puppies under 9 weeks of age or~~ weighing less than [41][81] lbs. DO NOT ALLOW CHILDREN TO APPLY PRODUCT. DO NOT TOUCH TREATED AREA UNTIL DRY. DO NOT ALLOW ADULTS, CHILDREN OR OTHER PETS TO TOUCH TREATED AREA UNTIL DRY. DO NOT USE ON CATS OR RABBITS. DO NOT USE ON ANIMALS OTHER THAN DOGS. Do not apply more than [once a month][every 30 days][every 4 weeks].

Do not allow your dog to ingest this product. Do not split applicators between dogs. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Do not apply more than one applicator per treatment for one dog regardless of the dog's weight. Overdosing your dog can result in serious illness. Do not bathe your dog within the first 24 hours after the product has been applied. Remember, your dog needs to be dry at the time **FRONTLINE® Shield for Dogs** is applied and remain dry 24 hours after application.

If your dog is exhibiting signs of and/or is being treated for skin problems, talk to your veterinarian before applying any topical flea and tick control product. Do not apply more often than [once a month][every 30 days][every 4 weeks].

FREQUENCY OF APPLICATION

[Fleas, flea eggs, ~~flea pupae,~~ flea larvae,][All life stages of fleas], ticks, and chewing lice infestations can be controlled with monthly applications of **FRONTLINE® Shield for Dogs**. Stable flies and mosquitoes are repelled by **FRONTLINE® Shield for Dogs** for [one month][30 days][4 weeks]. Sand flies are [killed][repelled] for 3 weeks by **FRONTLINE® Shield for Dogs**. **Fleas:** **FRONTLINE® Shield for Dogs** kills adult fleas for [one month][30 days][4 weeks]. Apply [monthly][every 30 days][every 4 weeks] if your dog has fleas that may cause flea allergy dermatitis (FAD), or if re-infestation is likely.

Ticks: **FRONTLINE® Shield for Dogs** can kill ticks for [one month][30 days][4 weeks]. Apply monthly where tick control is consistently needed.

Lice: **FRONTLINE® Shield for Dogs** can kill chewing lice for [one month][30 days][4 weeks]. Apply [monthly][every 30 days][every 4 weeks] where lice control is consistently needed.

Mites: **FRONTLINE® Shield for Dogs** aids in the control of sarcoptes and mite infestations ~~and that may cause sarcoptic mange.~~

Stable flies and Mosquitoes: When applied [monthly][every 30 days][every 4 weeks], **FRONTLINE® Shield for Dogs** repels and prevents blood feeding by stable flies and mosquitoes.

[**Stable flies:** **FRONTLINE® Shield for Dogs** kills stable flies for [one month][30 days][4 weeks].]

FRONTLINE® Shield for Dogs completely breaks the flea life cycle when used [on a monthly basis][every 30 days][every 4 weeks].

Wait at least 30 days before re-application of **FRONTLINE® Shield for Dogs**. Avoid contact with treated area until dry. **FRONTLINE® Shield for Dogs** remains effective even after bathing, water immersion, or exposure to sunlight. A monthly application of **FRONTLINE® Shield for Dogs** kills existing fleas and prevents new fleas from developing; kills all stages of ticks and chewing lice; and repels mosquitoes and stable flies. Do not apply more than once a month.

Comment [S09]: Since stable flies and mosquitos are addressed together two lines before this, will make this line optional.

Single Applicator Insert {Right Inner Panel}

Research demonstrates that **FRONTLINE® Shield for Dogs** remains effective even after bathing, water immersion, or exposure to sunlight for 24 hours after application.

PESTICIDE STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

STORAGE: Store unused product in original container only in a cool dry place, out of reach of children and animals.

PESTICIDE DISPOSAL and CONTAINER HANDLING: Non-refillable container. Do not reuse or refill this container. **If empty:** Place in trash or offer for recycling, if available.

If partly filled: Call your local solid waste agency or 1-800-422-9874 for disposal instructions. Never place unused product down any indoor or outdoor drain.

How Supplied

For easy and convenient application, **FRONTLINE® Shield for Dogs** is available in sizes for [use on] large dogs ONLY ~~9 weeks or older and~~ 41-80 lbs., and extra-large dogs ONLY ~~9 weeks or older and~~ 81-120 lbs.

WARRANTY

Seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. To the extent consistent with applicable law, buyer assumes all risk of use and handling of this material when such use and handling are contrary to the label instructions.

Questions or Comments?

Call: 1-800-660-1842

Monday-Friday, 8am-8pm EST

EPA Reg. No. 65331-9

Single Applicator Insert {Back Panel}**FRONTLINE® Shield for Dogs****How to Apply:**

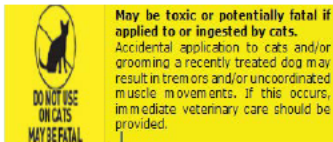
- (1) **TO OPEN:** Use scissors to cut along line of single blister, then pull apart foil and remove the applicator. Or, fold on line at corner, tear and open at slit and remove the applicator.
- (2) **HOLD** applicator upright away from you and your dog's face, cut applicator tip with scissors to open. Do not get the product in your dog's eyes or mouth.
- (3) **APPLY FRONTLINE® Shield for Dogs:**
Part dog's hair until skin is visible. Place applicator tip directly against exposed skin. [For large-sized dogs ONLY ~~9 weeks or older and~~ weighing 41-80 lbs].: [Apply the product evenly to three spots on the dog's back, starting between the shoulder blades and continuing on to the second and third spots, squeezing the applicator until empty. Ensure that FRONTLINE® Shield for Dogs is not applied superficially on dog's hair]. [For extra-large dogs ONLY ~~9 weeks or older and~~ weighing 81-120 lbs].: [Apply the product evenly to four spots on the dog's back, starting between the shoulder blades and continuing on to the second, third and fourth spots, squeezing the applicator until empty. Ensure that FRONTLINE® Shield for dogs is not applied superficially on dog's hair. Do not apply more than one applicator per treatment for one dog regardless of the dog's weight].

(2) Illustration
of scissors
cutting open
applicator

(3) Illustration
of product being
applied to a dog
in 3 or 4 spots

{Note to the Reviewer: A box labeled "Side Effects" will be placed immediately above the cat warning box on the back panel}.

Side Effects: Monitor your dog after application. Side effects, although very rare, may include signs of skin irritation such as redness, scratching, or other signs of discomfort. If these or other side effects occur, consult your veterinarian or call 1-800-660-1842.



{Note to the Reviewer: A 1.5 cm x 1.5 cm cat prohibition icon in yellow with black images will be located inside a box at the lower right hand corner of the back panel.}

Merial, Inc.
3239 Satellite Blvd.
Duluth, GA 30096-4640, USA

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Questions or Comments? Call: 1-800-660-1842 Monday-Friday, 8am-8pm EST

Made in France
EPA Reg. No. 65331-9
EPA Est. No.

[FRONT]

(Adult Tick
pictogram)(Stable Fly
pictogram)

See other side for more

FRONTLINE® Shield for Dogs(Applicator
pictogram)(Adult Flea
pictogram)

Some tips and other information:

(Mosquito
pictogram)(Flea eggs
and -larvae
and pupae
pictograms)(Chewing
Lice
pictogram)(Sand Fly
pictogram)**DO NOT USE ON CATS – MAY BE FATAL.**

To successfully treat fleas, ticks, and chewing lice, and repel mosquitoes and stable flies, all dogs must be treated with their own dose of **FRONTLINE® Shield for Dogs**.

Apply according to label instructions, ensuring the product is applied to the skin. Do not apply on top of the haircoat. It may be helpful to remove the collar before application, so it doesn't absorb the product.

Remember, your dog needs to be dry at the time **FRONTLINE® Shield for Dogs** is applied and remain dry 24 hours after application.

Verify applicator is empty after applying to your dog.



{Back}
Calendar Reminder Stickers

To ensure continued protection of your dog, use these stickers as a reminder to apply and re-purchase **FRONTLINE® Shield for Dogs**.

After treating your dog for the first time, peel off the sticker and place on your calendar that day. Place the remaining stickers on your calendar as a reminder to apply **FRONTLINE® Shield for Dogs** [monthly][every 30 days][every 4 weeks]. Don't forget to re-purchase!

6 months
Use all 6 stickers

3 months
Use all 3 stickers

5 stickers that read, "APPLY **FRONTLINE® Shield**", with the 6th sticker "Re-purchase **FRONTLINE® Shield**".

QUESTIONS? Contact your veterinarian or call our technical experts at 1-800-660-1842, Monday-Friday, 8am-8pm. For more information, visit (www.FRONTLINE-ACTIVE.com) (www.FRONTLINE.com).

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Reason to Issue: Label Amendment

Date: 09/11/2018
Supersedes: 07/31/2017

Label of Individual Applicator

{Note to Reviewer: Individual applicators are contained inside the child-resistant blister package.}

FRONTLINE® Shield for Dogs

6.01% Fipronil
44.88% Permethrin
1.8% Pyriproxyfen

For Dogs ~~& puppies~~ ONLY ~~9 weeks or older and~~ [41-80][81-120] lbs.

EPA Reg. No. 65331-9

**KEEP OUT OF REACH OF CHILDREN
WARNING**

Lot No.

[0.135][0.203] fl. oz.



Reason to Issue: Label Amendment

Date: ~~09/11/16~~ 09/11/2018
Supersedes: 07/31/2017

Blister Package

For external use only

FRONTLINE® Shield for Dogs

[0.035][0.203] fl. oz

KEEP OUT OF REACH OF CHILDREN

WARNING

Read accompanying label before use

Lot No.

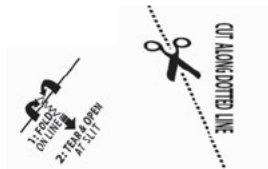


Illustration of dog with 3 or 4 arrows pointing to dog's back showing where to apply product



Alternate Marketing Text: Optional variations Appear in Brackets

(Note to reviewer: The final label may include some or all of the optional text for each claim)

Multiple Infestations

- Kills ~~and repels~~ fleas and ticks [for an entire month] including **Deer ticks, Brown dog ticks, American Dog ticks, and Lone Star ticks**
- Repels ~~and kills fleas~~ [ticks][mosquitoes][sand flies][stable flies] ~~flying insects~~.
- Repels mosquitoes for ~~up to~~ 4 weeks][30 days][one month]
- Repels mosquitoes and [kills][repels][sand flies][stable flies]
- Kills ticks which may transmit Lyme Disease, ~~canine~~ Ehrlichiosis, Anaplasmosis, Rocky Mountain Spotted Fever, Babesiosis, or cause tick paralysis
- [Kills][Controls] existing infestations and prevents re-infestations of fleas and ticks
- Long-lasting for [1 month][30 days][4 weeks] against fleas and ticks
- Re-infestation of fleas, ticks, and chewing lice is prevented for [a][one][month][30 days][4 weeks]
- After application, **FRONTLINE® Shield** spreads over the dog's body to provide [full body][all over] protection against fleas, ticks, mosquitoes, stable flies, and chewing lice
- **FRONTLINE® Shield for Dogs** provides ongoing protection [against fleas, ticks, stable flies, and chewing lice] for [at least][one month][30 days][4 weeks].
- **FRONTLINE® Shield for Dogs** provides efficacy against [fleas][and][ticks]
- Effective monthly treatment of fleas and ticks.
- ~~Fleas [and ticks] do not have to bite to die.~~
- Easy and effective control of fleas and ticks that lasts [1 month][30 days][4 weeks].
- Using the [patented][trademark] applicator, **FRONTLINE® Shield** is specially designed to spread over the dog's body providing effective control of fleas and ticks
- Prevents reinfestation of [fleas][ticks] for ~~up to~~ [one month][30 days][4 weeks]
- Monthly treatment is recommended for optimal control and prevention of fleas and ticks
- Proven treatment technology for the [control of flea infestations][control of ticks][repellency of ticks][repellency of mosquitoes][control of stable flies][repellency of stable flies][control of chewing lice][control of sand flies][repellency of sand flies]
- **FRONTLINE® Shield** uses [different][multiple] modes of action to [prevent fleas from developing][kill and repel ticks][kill fleas and chewing lice][kill and repel stable flies][repel mosquitoes][kill and repel sand flies]
- For convenient, long-lasting ~~up to~~ [one month][30 days][4 weeks] control of fleas, ticks, and chewing lice.
- [When] Applied topically on a monthly basis, **FRONTLINE® Shield for Dogs** kills existing fleas and prevents new fleas from developing; kills ticks and chewing lice, aids in control of sarcoptes ~~mange~~ mites, and [repels][inhibits blood feeding by] stable flies, sand flies and mosquitoes.
- **FRONTLINE® Shield** contains the active ingredients fipronil, permethrin and pyriproxyfen, which control infestations caused by fleas, ticks and chewing lice; and repels [against] stable flies and mosquitoes.
- To kill fleas and ticks and prevent fleas from developing
- To repel and prevent blood-feeding ticks, mosquitoes, sand flies and stable flies
- To kill chewing lice and to aid in control of sarcoptes ~~mange~~ mites
- Kills fleas, ticks, and chewing lice, and stable flies
- Repels [and prevents blood feeding by] stable flies and mosquitoes for ~~up to~~ [a month][one month][30 days][4 weeks]
- Kills [all stages] fleas and ticks
- Kills [all stages] of [ticks][and][chewing lice] and repels mosquitoes and stable flies.
- Repels ticks, stable flies and mosquitoes
- Repels sand flies for up to 3 weeks

- For the control and prevention of flea [and chewing lice] infestations
- Flea, tick, and chewing lice infestations can be controlled with monthly applications of **FRONTLINE® Shield for Dogs**.
- Stable flies and mosquitoes are [also] repelled by **FRONTLINE® Shield for Dogs**.
- Monthly application against fleas and ticks
- Kills fleas and ticks for ~~up to~~ [one month][an entire month]
- Monthly application is recommended for control and prevention of fleas and ticks
- **30-Day Prevention [Protection] [-of Fleas and Ticks]**.
- ~~Up to~~ [One month][30 days][4 weeks] of long-lasting flea and tick control for your dog
- Long-lasting control of fleas, ticks, and lice, and repellency of mosquitoes and stable flies for [one month][30 days][4 weeks]
- **FRONTLINE® Shield for Dogs** is indicated for the prevention and control of fleas, ticks, and ~~chewing lice~~ on [dogs and puppies ONLY 9 weeks of age or older and 41-80 lbs.][dogs and puppies ONLY 9 weeks of age or older and 81-120 lbs.].
- **FRONTLINE® Shield for Dogs** kills and repels stable flies and sandflies, and repels mosquitoes
- Kills fleas, ticks, chewing lice, and aids in control of sarcoptes ~~esic-mange~~ mites
- Repels ticks and mosquitoes
- Kills Fleas, Flea eggs, and Flea larvae, Ticks, Stable Flies, Sand flies and Lice and aids in the control of ~~sarcoptes~~ mites
- Stops existing infestations and prevents re-infestations of [fleas][ticks][chewing lice]
- LONG-LASTING CONTROL for ~~up to~~ [one month][30 days][4 weeks] of [FLEAS][TICKS][MOSQUITOES][SAND FLIES][STABLE FLIES][LICE]
- [Fleas, flea eggs, ~~flea pupae~~, flea larvae, ~~]~~ **[All flea life stages.]** ticks, and chewing lice infestations can be controlled with monthly applications of **FRONTLINE® Shield for Dogs**.
- The active ingredients in **FRONTLINE® Shield** provide for [long-lasting][control] ~~up to one month~~ [for] [30 days][4 weeks][one month][one month of long-lasting] ~~up to one month of long-lasting~~ [control] of fleas, ticks, mosquitoes, stable flies, and chewing lice on dogs.
- Convenient, [long-lasting][for] ~~up to~~ [one month][30 days][4 weeks] ~~spot-on-topical~~ for treatment of fleas, ticks, and chewing lice, and repellency of mosquitoes, sand flies and stable flies.
- To [successfully] treat fleas, ticks, and chewing lice, and repel mosquitoes, sand flies and stable flies, all dogs must be treated with their own dose of **FRONTLINE® Shield for Dogs**.

[Fleas]

- ~~Kills fleas within 6 hours, beginning 2 days after treatment with FRONTLINE® Shield.~~
- Prevents fleas on treated dogs from infesting your home
- Prevents fleas from developing
- Prevents fleas, flea eggs and flea ~~larvae~~ ~~pupae~~ from developing
- Kills fleas on dogs and continues to prevent infestations for a month
- ~~Works [fast][quickly], starts killing fleas in 5 minutes.~~
- Kills fleas [before they lay eggs][that may transmit bartonellosis and tapeworm disease]
- Kills fleas which may cause flea allergy dermatitis
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs with **FRONTLINE® Shield** kills fleas ~~that may cause this condition and may reduce the incidence of this condition.~~
- **FRONTLINE® Shield** kills existing fleas on dogs.
- Re-infesting fleas are killed quickly with protection against further flea infestation lasting four weeks.
- ~~May reduce the incidence of flea allergy dermatitis.~~

- Kills [newly emerged] fleas [before they lay eggs] for [up to][one month][30 days][4 weeks].
- **FRONTLINE® Shield for Dogs** can kill adult fleas and lasts for [up to][one month][30 days][4 weeks]. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAD), or if reinfestation is likely.
- Kills newly emerged adult fleas prior to egg laying.
- Kills fleas that may transmit bartonellosis, [~~(tularemia)~~][and tapeworm] [infections].
- Kills fleas that may transmit bartonellosis and tularemia.
- Acts to kill fleas that may transmit bartonellosis and tularemia.
- Kills fleas that may serve as an intermediate host for tapeworms (*Dipylidium caninum*).
- Kills fleas that may serve as an intermediate host for cysticercoids of tapeworms.
- Kills fleas that may serve as hosts for life cycle intermediates of tapeworms.
- Kills (adult) fleas that may cause [Flea Allergy Dermatitis (FAD)][or][flea-bite anemia].
Fleas do not have to bite to die.
- **FRONTLINE® Shield for Dogs** kills fleas that may cause FAD (Flea Allergy Dermatitis).
- Kills [adult] fleas.
- Easy to apply, control of [for] fleas that lasts [up to][one month][30 days][4 weeks].
- **FRONTLINE® Shield for Dogs** kills fleas on your dog.
- Once a month topical flea control for [dogs and puppies ONLY 9 weeks of age or older and 41-80 lbs][dogs ONLY 9 weeks of age or older and 81-120 lbs].
- **FRONTLINE® Shield for Dogs** is indicated for the prevention and control of fleas on [dogs ONLY 9 weeks or older and weighing 41-80 lbs.][dogs ONLY 9 weeks or older and weighing 81-120 lbs.].
- One application prevents further flea infestations for [up to][one month][30 days][4 weeks].
- Monthly treatment [all year] is recommended for control and prevention of fleas.
- Provides ongoing protection against fleas.
- Stops existing flea infestations by killing adult fleas [and preventing new fleas from developing].
- Kills fleas before they lay eggs.
- [Prevents] re-infestations by killing adult fleas [before they lay eggs].
- Treatment with **FRONTLINE® Shield** kills fleas which may cause flea allergy dermatitis (FAD) or flea bite hypersensitivity.
- Use flea [prevention][protection] year-round.
- **FRONTLINE® Shield for Dogs** kills flea eggs and larvae for [up to][4 weeks][30 days][one month].
- **FRONTLINE® Shield for Dogs** [~~completely~~] breaks the flea life cycle when used [on a monthly basis][every 30 days][every 4 weeks][before they become biting adults].
- Prevents establishment of new infestations
- **FRONTLINE® Shield for Dogs** prevents flea eggs from hatching
- Kills flea eggs and flea larvae to help prevent future re-infestations
- [Prevents][Stops] flea eggs from developing into biting adults for [one month][30 days][4 weeks].
- [Prevents][Stops] all flea stages [eggs][~~pupae~~][larvae][adult] from developing [to help prevent re-infestation].
- Inhibits the development of immature flea stages [and prevents them from reaching the biting adult stage]
- Provides multi-stage flea control [effectively breaking the flea life-cycle] for lasting control of flea populations.
- Fleas do not have to bite to [die][be controlled][be killed][be inhibited from developing].
- Prevents development of [immature flea stages][flea eggs][flea larvae][~~flea pupae~~], breaking the flea life cycle.
- **Fleas: FRONTLINE® Shield for Dogs** kills adult fleas for [one month][30 days][4 weeks]. Apply [monthly][every 30 days][every 4 weeks] if your dog has fleas that may

Comment [S010]: Moved to multiple infestations sect on to add ticks to the claim.

cause flea allergy dermatitis (FAD), or if re-infestation is likely.

- **FRONTLINE® Shield for Dogs** kills existing fleas and prevents new fleas from developing.
- A [monthly][30 day][4 week] application of **FRONTLINE® Shield for Dogs** kills existing fleas and prevents new fleas from developing.

[Ticks]

- [Kills][and][repels] all stages of ticks that infest dogs.
- [Kills][and][repels] ticks [which may cause][which may transmit] [Lyme disease], [canine Ehrlichiosis], [Anaplasmosis], [Babesiosis], [Tick Paralysis], [Rocky Mountain Spotted Fever], [Southern Tick Associated Rash Illness], [or cause tick paralysis].
- [Kills][and][repels] ticks for [up to] [one month][30 days][4 weeks].
- **FRONTLINE® Shield for Dogs** [kills][repels] all stages of ticks, including Deer ticks, Brown dog ticks, American dog ticks and Lone Star ticks.
- Kills and repels ticks.
- [Kills][and][repels] the tick vectors that may transmit Lyme disease, Rocky Mountain spotted fever, ehrlichiosis, babesiosis, and anaplasmosis heartworm disease.
- **Ticks: FRONTLINE® Shield for Dogs** can [kill][repel] ticks for [one month][30 days][4 weeks][up to] a month]. Apply [monthly][every 30 days][every 4 weeks] where tick control is consistently needed.
- [Kills][and][repels] Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks [that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis and anaplasmosis].
- [Kills][and][repels] ticks including Deer ticks [that may transmit Lyme disease], American dog ticks [that may transmit Rocky Mountain Spotted Fever], Brown dog ticks and Lone Star ticks [that may transmit ehrlichiosis] for [up to] [one month][30 days][4 weeks].
- [Kills][and][repels] Brown dog ticks (*Rhipicephalus* spp.), American dog ticks (*Dermacentor variabilis*), Deer ticks (*Ixodes* spp.), and Lone Star ticks (*Amblyomma americanum*) for [up to] [one month][4 weeks].
- [Kills][and][repels] *Amblyomma americanum* (Lone Star tick) for [up to] [one month][30 days][4 weeks].
- Monthly application against ticks.

Comment [S011]: Corrected previous error. heartworm disease is not transmitted by ticks.

[Mosquitoes, stable flies and sand flies]

- Repels mosquitos, sand flies and stable flies.
- Repels and inhibits blood feeding by stable flies, sand flies and mosquitoes.
- **Stable flies and mosquitoes:** When applied [monthly][every 30 days][every 4 weeks], **FRONTLINE® Shield for Dogs** [repels][and][prevents blood feeding by] stable flies and mosquitoes [for][up to] [4 weeks][one month][30 days][a month].
- **Stable flies:** **FRONTLINE® Shield for Dogs** kills stable flies for [one month][30 days][4 weeks].
- Stable flies and mosquitoes are repelled by **FRONTLINE® Shield for Dogs** for [one month][30 days][4 weeks].
- Repels and prevents blood-feeding by stable flies and mosquitoes for [up to] [a month][30 days][4 weeks].
- Repels mosquitoes for [up to] [one month][four (4) weeks].
- Prevents blood feeding by mosquitoes.
- Repels mosquitos that may carry vector borne diseases such as [heartworm disease][and][West Nile].
- Prevents blood feeding by stable flies.
- Kills stable flies.
- Repels and prevents [inhibits] blood-feeding by stable flies.

- Repels and prevents [inhibits] blood-feeding by sand flies for **up to** 3 weeks.
- [Prevents blood-feeding by][and repels] mosquitoes.
- Repels stable flies.
- [Repels][Kills] sand flies for up to 3 weeks.
- Repels [annoying][bothersome][nuisance][stable flies][and][sand flies for up to 3 weeks].
- [Prevents][inhibits] blood-feeding by [stable flies][sand flies for up to 3 weeks].
- Repels mosquitoes which may [carry][be (a) vector(s) of heartworm (*Dirofilaria immitis*)] for **up to** [one month][30 days][4 weeks].
- Repels and prevents blood-feeding by [stable flies][sand flies for **up to** 3 weeks].
- Sand flies are [killed][repelled] for 3 weeks by **FRONTLINE® Shield for Dogs**.

[Chewing lice and Sarcop~~tes~~~~is~~~~e~~~~mange~~ mites]

- [For treatment of][Treats and controls][Provides effective control of][For treatment of infestations with][Kills][Stops existing] chewing lice [infestations].
- Kills chewing lice [for one month][30 days][4 weeks].
- **[Chewing] Lice: FRONTLINE® Shield for Dogs** can kill chewing lice for **up to** [one month][30 days][4 weeks]. Apply [monthly][every 30 days][every 4 weeks] where lice control is consistently needed.
- **Sarcop~~tes~~~~is~~~~e~~~~mange~~ mites: FRONTLINE® Shield for Dogs** aids in the control of sarcop~~tes~~~~is~~~~e~~~~mange~~ mites that may cause sarcoptic mange.
- **FRONTLINE® Shield for Dogs** aids in [the] control of sarcop~~tes~~~~is~~~~e~~~~mange~~ mite infestations [that may cause sarcoptic mange].
- [When applied monthly,] **FRONTLINE® Shield for Dogs** aids in the control of sarcop~~tes~~~~is~~~~e~~~~mange~~ mites that may cause sarcoptic mange.
- Aids in the control of sarcop~~tes~~~~is~~~~e~~~~mange~~ mite [infestations].
- [Also] Kills chewing lice and aids in the control of sarcop~~tes~~~~is~~~~e~~~~mange~~ mites [that may cause sarcoptic mange].
- Controls existing chewing lice infestations.
- For control and prevention of chewing lice [infestations].
- Stops existing chewing lice infestations.
- Prevents and controls chewing lice [infestations].
- Provides control of chewing lice [infestations].
- Kills chewing lice and prevents further infestations.
- For control and prevention of [infestations with] chewing lice.
- **Sarcoptes Mites: FRONTLINE® Shield for Dogs** aids in the control of sarcop~~tes~~~~is~~~~e~~~~mange~~ mite infestations [that may lead to sarcoptic mange].

[Miscellaneous]

- **FRONTLINE® Shield for Dogs** is [water-resistant][is waterproof] and remains effective following bathing, shampooing, swimming [water immersion] or after exposure to rain or sunlight for 24 hours after application.
- [Research demonstrates that] **FRONTLINE® Shield for Dogs** remains effective even after bathing, water immersion, or exposure to sunlight for 24 hours after application.
- Convenient topical treatment for dogs that enjoy the outdoors.
- [Easy and convenient][Convenient][to use][Easy to apply][**topical spot-on**] application(s).
- Persistent [sustained] efficacy through [one month][30 days][4 weeks].
- Protects for [one month][30 days][4 weeks].
- Convenient [easy to apply] topical treatment [with patented applicator][that allows application down to the skin][for dogs].
- [Patented] applicator [trademark] for easy application directly to the skin.
- Quick-drying.

- For easy and convenient application, **FRONTLINE® Shield for Dogs** is available in sizes for large dogs ONLY ~~9 weeks or older and~~ 41-80 lbs. [0.135 fl. oz.][4.0 ml], and extra-large dogs ONLY ~~9 weeks or older and~~ 81-120 lbs. [0.203 fl. oz.][6.0 ml].
- Easy, ~~spot-on~~ [topical] application.
- Non-greasy.
- [Formulated] for dogs that [enjoy][love] the outdoors.
- Waterproof.
- [For use] Can be used on dogs ~~and puppies~~ ONLY ~~9 weeks or older and~~ weighing at least [41][81] lbs.
- Water-resistant.
- Convenient to use.
- [1] applicator(s) [0.135 fl. oz.][4.0 ml].
- [3][6] applicator(s) [0.203 fl. oz.][6.0ml].
- [1][3][6] applicator(s).
- [1][3][6] monthly dose(s) [application(s)].
- This product is for use on dogs ~~and puppies~~ ONLY [~~9 weeks or older and~~ 41-80 lbs.][~~9 weeks or older and~~ 81-120 lbs.]
- ~~[For use][Can be used] on Dogs and Puppies ONLY 9 weeks or older and weighing [at least][41][81] lbs.]~~
- Stops existing infestations and prevents establishment of new infestations.
- Convenient, [long-lasting][for up to one month][30 days][4 weeks][one month] ~~spot-on~~ [topical] treatment of fleas, ticks, and chewing lice, and repellency of mosquitoes, sand flies and stable flies.
- Prevents (re-)infestation for [one month][30 days][4 weeks].
- Once monthly application.
- **FRONTLINE® Shield for Dogs** is brought to you by the makers of **FRONTLINE®**.
- Quick drying, non-greasy.
- No noticeable odors.
- Easy to use applicator makes treatment simple [trouble free, smooth] and comfortable for you and your ~~our~~ dog.
- [In] child-resistant packaging.
- Convenient [to use], easy to apply [topical solution].
- Water-proof [remains effective after bathing and swimming] for [~~up to~~][a month][one month][30 days][4 weeks].
- Remains effective after exposure to sunlight for 24 hours after application.
- **FRONTLINE® Shield for Dogs** remains effective even after bathing, water immersion, or exposure to [rain][or][sunlight] for 24 hours after application.
- Remains effective after exposure to rain and/or sunlight for 24 hours after application.
- Still works after bathing, swimming or exposure to sunlight for 24 hours after application.
- Maintains residual efficacy after bathing and swimming for 24 hours after application.
- Remains effective after bathing [and swimming][for a month][for one month][for ~~up to~~ four weeks][for ~~up to~~ 30 days] for 24 hours after application.
- For indoor and outdoor dogs.
- Convenient topical treatment for dogs that enjoy the outdoors.
- Illustration of flea life cycle.
- Illustration of tick life cycle.
- Illustration of mosquito life cycle.
- Illustration of stable fly life cycle.
- Illustration of *sarcoptes scabiei* ~~sarcoptic mange~~ mite life cycle.
- Illustration of chewing lice life cycle.
- Illustration of sand fly life cycle.
- Illustration of flea.
- Illustration of flea eggs and/or larvae ~~and/or pupae~~
- Illustration of tick.

Comment [S012]: Repetitive of bullet point 8 bullets above

| Reason to Issue: Label Amendment

Date: ~~09~~11/1~~0~~3/2018
Supersedes: 07/31/2017

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- Illustration of mosquito.
 - Illustration of ~~sarcoptes scabiei~~ ~~sarcoptic mange~~-mite.
 - Illustration of chewing lice.
 - Illustration of stable fly.
 - Picture or illustration of a dog [or puppy].
 - Picture or illustration of the Merial logo.
 - Picture or illustration of the primary package [applicators].

Pictograms (icon with slash through):

[Adult flea]

[Flea eggs]

[Flea larvae]

| ~~[Flea pupae]~~

[Adult tick]

[Chewing lice]

[Mosquitoes]

[Stable flies]

[Sand flies]

| ~~[Sarcoptes. Sarcoptic mange-mites]~~